



RECEIVED

JAN 09 2002

TECH CENTER 1600/2900 PATENT

ATTORNEY DOCKET NO. 06132/043002

1645  
#3

Certificate of Mailing: Date of Deposit: October 17, 2001

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Susan M. Barry

Printed name of person mailing correspondence

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Harold Kleanthous et al.

Art Unit: 1645

Serial No.: 09/895,913

Examiner: Not Yet Assigned

Filed: June 29, 2001

Customer No.: 21559

Title: Identification of Polynucleotides Encoding Novel Helicobacter  
Polypeptides in the Helicobacter Genome

Assistant Commissioner for Patents  
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449.

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application serial number 08/881,227, filed on June 24, 1997. The references listed below were submitted to and/or cited by the Office in the prior application and, therefore, copies of these references are not provided in this application. Three references submitted herewith, and indicated with asterisks on the Form PTO 1449, were not cited in the earlier application, and thus copies of these references are enclosed.

Submission of this statement is not a representation that a search has been made,

nor is information included in this statement an admission that the information is material to patentability.

5,116,821	05/26/92	Randall et al.
5,128,140	07/07/92	Chapura et al.
5,258,178	11/02/93	Cordle et al.
5,447,923	09/05/95	Catrenich et al.
5,476,669	12/19/95	Borody
5,514,660	05/07/96	Zopf et al.
5,538,729	7/23/96	Czinn
5,563,039	10/08/96	Goeddel et al.
5,567,594	10/22/96	Calenoff
5,610,060	03/11/97	Ward et al.
5,620,964	04/15/97	Roth et al.
5,679,769	10/21/97	Danishefsky et al.
5,753,630	05/19/98	Zopf et al.
WO 91/09049	27.06.91	PCT
WO 91/15572	17.10.91	PCT
WO 93/18150	16.09.93	PCT
WO 94/09823	11.05.94	PCT
WO 95/22987	31.08.95	PCT
WO 95/33482	14.12.95	PCT
WO 96/33732	31.10.96	PCT
WO 96/38475	05.12.96	PCT
WO 96/40893	19.12.96	PCT
WO 97/03359	30.01.97	PCT
WO 97/03360	30.01.97	PCT
WO 97/19098	29.05.97	PCT

WO 97/11182	27.03.97	PCT
WO 97/12908	10.04.97	PCT
WO 97/12909	10.04.97	PCT
WO 97/37044	09.10.97	PCT
WO 97/47646	18.12.97	PCT
WO 98/18323	07.05.98	PCT

Bazillou et al., "Serum Antibody Response to the Superficial and Released Components of *Helicobacter pylori*," Clin. and Diag. Lab. Immun. 1(3):310-317 (1994)

Borén et al., "Attachment of *Helicobacter pylori* to Human Gastric Epithelium Mediated by Blood Group Antigens," Science 262:1892-1895 (1993)

Borody et al., "Omeprazole enhances efficacy of triple therapy in eradicating *Helicobacter pylori*," Gut 37:477-481 (1995)

Bukanov et al., "Ordered Cosmid Library and High-Resolution Physical-Genetic Map of *Helicobacter pylori* Strain NCTC11638," Mol. Microbiology 11(3):509-523 (1994)

Clayton et al., "Sensitive Detection of *Helicobacter pylori* by Using Polymerase Chain Reaction," Journal of Clinical Microbiology 30:192-200 (1992)

Czinn et al., "Oral immunization against *Helicobacter pylori*", Infection and Immunity 59:2359-2363 (1991)

D'Elios et al., "T Helper 1 Effector Cells Specific for *Helicobacter pylori* in the Gastric Antrum of Patients with Peptic Ulcer Disease," The Journal of Immunology 158:962-967 (1997)

Doig et al., "Identification of Surface-Exposed Outer Membrane Antigens of *Helicobacter pylori*," Infection and Immunity 62:4526-4533 (1994)

Drouet et al., "Partial Characterization of an External Polysaccharide of *Helicobacter pylori* by Using an Immunoglobulin M Monoclonal Antibody," Infection and Immunity 61:2732-2736 (1993)

Farokhnia, "Antibody Specific for a Plasmid-Encoded Protein of *Helicobacter Pylori*," Thesis, Grad. School of The Texas Women's University, Department of Biology, p. 1-30

Fauchere et al., "Adherence of *Helicobacter pylori* Cells and Their Surface Components to HeLa Cell Membranes," Microbial Pathogenesis 9:427-439 (1990)

Ferrero et al., "Recombinant Antigens Prepared from the Urease Subunits of *Helicobacter* spp.: Evidence of Protection in a Mouse Model of Gastric Infection," Infection and Immunity 62:4981-4989 (1994)

Graham et al., "Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing," Annals of Internal Medicine 115:266-269 (1991)

Haas et al., "TnMax - a versatile mini-transposon for the analysis of cloned genes and shuttle mutagenesis", Gene 130:23-31 (1993)

Herszenyi et al., "Impaired Fibrinolysis and Increased Protease Levels in Gastric and Duodenal

Mucosa of Patients with Active Duodenal Ulcer," Am. J. Gastroenterology 92:843-847 (1992)

Husson et al., "Iron Acquisition by *Helicobacter pylori*: Importance of Human Lactoferrin," Infection and Immunity 61:2694-2697 (1993)

Illingworth et al., "Siderophore Production and Iron-regulated Envelope Proteins of *Helicobacter pylori*," Zbl. Bakt. 280:113-119 (1993)

Kaplan, "Autogenous Vaccination Against *Helicobacter pylori*," South African Medical Journal 83:922-92 (1993)

Lee et al., "Oral immunization with recombinant *Helicobacter pylori* urease induces secretory IgA antibodies and protects mice from challenge with *Helicobacter felis*", The Journal of Infectious Diseases 172:161-172 (1995)

Lipinska et al., "Sequence Analysis and Regulation of the htrA Gene of Escherichia Coli: A Sigma-32-independent Mechanism of Heat-inducible Transcription," Nucleic Acids Res. 16:10053-10067 (1988)

Mohammadi et al., "*Helicobacter*-Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," The Journal of Immunology 156:4729-4738 (1996)

Monath et al., "Development of Recombinant *Helicobacter pylori* Urease as an Oral Vaccine: Current Status," Gut 37 (Suppl. 1):A52, 205 (1995)

Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," Gut 39 (Suppl. 2):A44, 1B:24 (1996)

Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against *Helicobacter pylori*," Eur. J. Clin. Microbiol. Infect. Dis. 14:391-399 (1995)

Robinson et al., "Protection against a lethal influenza virus challenge by immunization with a haemagglutinin-expressing plasmid DNA", Vaccine 11:957-960 (1993)

Robinson et al., "Use of direct DNA inoculations to elicit protective immune responses", Vaccines 93, "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," Cold Spring Harbor Laboratory Press, 311-315 (1993)

Sherburne et al., "*Helicobacter pylori* Expresses a Complex Surface Carbohydrate, Lewis X," Infection and Immunity 63:4564-4568 (1995)

Taylor et al., "Use of Non-Radioactive DNA Probes For Detection of *Campylobacter Jejuni* and *Campylobacter Coli* in Stool Specimens," Molecular Cell Probes 4:261-271 (1990)

Taylor et al., "Construction of a *Helicobacter pylori* Genome Map and Demonstration of Diversity at the Genome Level," J. Bacteriol. 174(21):6800-6806 (1992)

Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of *Helicobacter pylori*," Scand. J. Gastroenterol. 28:934-938 (1993)

Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen *Helicobacter pylori*," Nature 388:539-547 (1997)

Ulmer et al., "Heterologous protection against influenza by injection of DNA encoding a viral protein", Science 259:1745-1749 (1993)

Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiologica Hungarica 38:164-165 (1991)

Haas et al., U.S. Serial No. 08/749,051, filed 11/14/96

Haas et al., U.S. Serial No. 08/831,309, filed 4/1/97

Haas et al., U.S. Serial No. 08/834,705, filed 4/1/97

Kleanthous et al., U.S. Serial No. 08/831,310, filed 4/1/97

Kleanthous et al., U.S. Serial No. 09/881,752, filed 6/18/01

Kleanthous et al., U.S. Serial No. 08/834,666, filed 4/1/97

Kleanthous et al., U.S. Serial No. 09/882,227, filed 6/15/01

Lee et al., U.S. Serial No. 08/568,122, filed 12/6/95

Michetti et al., U.S. Serial No. 09/426,328, filed 10/25/99

Michetti et al., U.S. Serial No. 09/955,739, filed 09/18/01

If there are any charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date: October 16, 2001

Susan M. Michaud  
Susan M. Michaud, Ph.D.  
Reg. No. 42,885

Clark & Elbing LLP  
176 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045



21559

PATENT TRADEMARK OFFICE

F:\06132\06132.043002 Information Disclosure Statement.wpd